DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

WARNING LETTER

WL-CIN-9562-01
September 6, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roger Brinser, Directory of Regulatory Affairs and Authorized Official
Sera-Tec Biologicals Limited Partnership
931 North Seventh Street
Harrisburg, PA 17102

Dear Mr. Brinser:

During an inspection of your plasma collection facility located at 210 Sheffield Center, Lorain, OH on July 24 through 27, 30, 31 and August, 2 2001 our FDA investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Part 600-680 as follows:

The failure to follow your firm's written procedures for the quality assurance activities [21CFR 606.100] as demonstrated by the following:

Failure to perform QA review of the SPE and RPR results on the Laboratory Requisition for Testing forms from 2/2/01 through 7/26/01.

Failure to review In Process Failure (error and accident) forms.

Failure to perform competency audits of employees

Failure to perform daily QA review of the refractometer records, refrigerator/freezer records, donor files and reactive unit log;

Failure to perform annual re-certification of the center physician and physician substitute.

Records of the performance of significant steps in the collection and storage of plasma were incomplete or inaccurate [606.160, 606.60] as demonstrated by the following:

Failure to document the initial out of range values on Haemonetics machines weight calibration records.

Failure to perform the annual calibration of the refrigerator used to store tetanus antigen and samples.

The failure to follow your written procedure for the performance of the arm preparation technique [640.64(e), 606.100(b), 606.20(a)].

The use of outdated reagents for the performance of the quality control of the Hematastat II [606.65(e)].

The failure to segregate tested and untested plasma products [606.40 (d)(2)].

The items listed above also demonstrate that employees were inadequately trained and/or supervised in the operations for which they were responsible [606.20(b)].

Neither the above-identified deviations nor the list of inspectional observations issued at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your plasma center. It is your responsibility to ensure that your firm is in compliance with all requirements of the Act and federal regulations.

You should take prompt action to correct the current deviations. Your failure to promptly correct the deviations may result in regulatory action without further notice. Such action includes the suspension or revocation of your firm's license, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please provide evidence that you have corrected the problems such as copies of finalized SOPs or new forms that are implemented to correct the problems.

We have received the written response to the FDA-483, Inspectional Observations that was issued in July 2001. Generally, the response appears adequate however we have some concern that not all individuals who were involved with these issues were properly re-trained. Specifically, we do not find that employee [redacted] was properly retrained with respect to FDA-483 items 1 and 2. We also note that the [redacted] does not appear to have signed the checklist that was submitted to document the re-certification (FDA-483 item 5). Finally, we find that many of the problems from the inspection were QA related. How does your company plan to monitor future QA activities at this center and at your other centers?

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097 Attn: Stephen J. Rabe, Compliance Officer. Please contact Mr. Rabe if you are still interested in scheduling meeting to discuss this inspection.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District Office